DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2016

GS Medical Company, Ltd.
% Mr. Barry E. Sands
President
RQMIS, Incorporated
29 Water Street, Suite 305
Newburyport, Massachusetts 01950

Re: K153517
Trade/Device Name: AnyPlus® Cervical PEEK Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: May 26, 2016
Received: May 27, 2016

Dear Mr. Sands:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153517

Device Name
AnyPlus® Cervical PEEK Cage System

Indications for Use *(Describe)*
The AnyPlus® Cervical PEEK Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. AnyPlus® Cervical PEEK cages are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. AnyPlus® Cervical PEEK cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

GS Medical Co., Ltd.

AnyPlus® Cervical PEEK Cage System

Manufacturer:	GS Medical Co., Ltd. 90, Osongsaengmyeong 4-ro Osong-eup Cheongwon-gun Chungcheongbuk-do 363-951 Korea
Date:	March 20, 2016
Submitted by:	GS Medical Co., Ltd
Company Contact	Marcin Niemiec
US Agent Information Official Correspondent	RQMIS Inc. Mr. Barry E. Sands 110 Haverhill Road, Suite 526 Amesbury, MA 01913 Ph: 978-358-7307 www.rqmis.com
Proprietary Name:	AnyPlus® Cervical PEEK Cage System
Performance standards:	The AnyPlus® Cervical PEEK Cage System was non-clinically tested according to the ASTM 2077-11 and ASTM F2267-04 performance standards.
Regulation: Common/Usual Name: Classification name: Review Panel: Product Code: Device Class:	21 CFR 888.3080 Cervical Spinal Fusion Device, IBF Device Intervertebral body fusion device – Cervical Orthopedic ODP Class II
Substantial Equivalence:	Substantial equivalence for the AnyPlus® Cervical PEEK Cage System is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices.
Predicate Devices:	• K082801 US Spine Phantom Cervical Cage (primary) • K091873 SpineArt Tryptik Cervical Cage (secondary) The subject device is substantially equivalent to similar previously cleared devices.

Device Description:	The AnyPlus® Cervical PEEK Cage System is designed for restoring the height of the intervertebral space after resection of the disc. AnyPlus® Cervical PEEK Cage System consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The intervertebral body fusion devices are made of poly-ether-ether-ketone (PEEK Optima LT1) body with the X-ray (radio-opaque) markers made of Tantalum. The AnyPlus® Cervical PEEK Cage System are radiolucent allowing X-ray visualization to verify device placement. AnyPlus® Cervical PEEK Cage System is supplied non-sterile and is intended for single use only. AnyPlus® Cervical PEEK Cage System is designed for interbody stabilization of the cervical spine.
Intended Use:	The AnyPlus® Cervical PEEK Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. AnyPlus® Cervical PEEK cages are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. AnyPlus® Cervical PEEK cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.
Summary of Technological Characteristics	The AnyPlus® Cervical PEEK cages are designed for restoring the height of the intervertebral space after resection of the disc. The AnyPlus® Cervical PEEK cages consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The implants are made of polyether-ether-ketone (PEEK) body with the x-ray markers made of Tantalum. The intended use, technological characteristics, mode of action and materials of construction are the same as those of the referenced predicate devices
Non-Clinical Testing	The AnyPlus® Cervical PEEK cages were tested according to the ASTM 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM 2267. All performance test results were equivalent to or higher than a legally marketed predicate device.
Clinical Testing	No clinical testing was performed.
Conclusion	The AnyPlus® Cervical PEEK cages have the same intended use and similar indications, principles of operation, and technological characteristics as the predicate devices. The minor differences in the designs do not raise any new questions of safety or effectiveness. Performance data demonstrates that the AnyPlus® Cervical PEEK cages are as safe and effective as the predicate devices. Thus, the AnyPlus® Cervical PEEK cages are substantially equivalent to the predicate devices.